MAY - 4 2012

K120362

3. 510(K) SUMMARY

1. Applicant/Sponsor: Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Establishment Registration No.: 1056629

2. Contact Person: Lucinda Gerber, BA (Hons)
Regulatory Affairs Associate
Corin USA
813-977-4469
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3. Date: February 3, 2012

4. Proprietary Name: Metafix Femoral Stem for Hemi-arthroplasty

5. Common Name: Hip Prosthesis

6. Product Codes: LZO, KWL, KWY

7. Classification Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21CFR 888.3390)

Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21CFR 888.3360)

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353)

8. Legally Marketed Devices to which Substantial Equivalence is claimed:

- Corin Metafix Femoral Stem (K082525)
- Corin Optimom Modular Heads (K111911)
- Corin Bipolar Heads (K925897)
- Taper Fit Total Hip System (K003666)

9. Device Description:

The Corin Metafix Hip Stem is a titanium femoral hip stem featuring a 12/14 tapered male trunnion for assembly with modular femoral head components. The stem is manufactured from Titanium ($TiAl_6V_4$) alloy for surgical implant applications, conforming to ASTM F136-11 and is coated with plasma sprayed hydroxyapatite conforming to ASTM F-1185-03(2009). The stem is indicated for use with Corin CoCr modular femoral heads and ceramic modular femoral heads with a 12/14 taper. (NOTE : the ceramic modular heads are not subject of this 510(k) submission.) The stem is available in nine sizes, each available in three offsets including standard (135°), lateralized 135°, and standard (125°).

The Corin Bipolar Head (K925897) is comprised of an outer CoCr shell, an inner liner of ultra high molecular weight polyethylene (UHMWPE), and an inner CoCr head. The Bipolar head is available in a range of outer diameter sizes and a variety of head offsets and is compatible with all Corin 12/14 taper femoral stems. The Corin Optimom Modular Head (K111911) is a polished, truncated CoCr alloy sphere with a high tolerance internal female taper and is available in a range of diameters with a variety of offsets. It is compatible with Corin 12/14 taper titanium and stainless steel femoral stems. The Bipolar and the Optimom Modular Heads are indicated for hip hemi-arthroplasty.

The purpose of this submission is to modify the labeling for the Metafix Femoral Hip Stem to include hip hemi-arthroplasty to the indications for use when the stem is mated with a Corin CoCr hemi-arthroplasty femoral head.

10. Intended Use / Indications:

The indications for the Corin Metafix Hip Stem as a total hip arthroplasty and, when used in combination with Corin hemi-arthroplasty femoral heads, as a hemi-arthroplasty, include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin Metafix Hip Stem is intended for cementless use only.

11. Summary of Technologies/Substantial Equivalence:

The Corin Optimom Modular heads and the Corin Bipolar heads are identical to the predicate femoral heads in intended use/indications for use, design, materials and sizes. The Corin Metafix Femoral Stem for Hemi-arthroplasty is identical to the Metafix Femoral Stem cleared in K082525 in materials and sizes. The subject of this submission, Metafix Femoral Stem for Hemi-arthroplasty, is for a modification of the indications for use to include hip hemi-arthroplasty with the addition of compatible components. The inner 26mm Eurocone CoCr femoral head of the Corin Bipolar Head (K925897, K003666), is manufactured of the same material, is similar in design and within the range of the 22mm and 28mm Eurocone CoCr modular heads that were previously indicated as compatible components for use with the Metafix Femoral Stem (K082525). The Optimom Modular head is indicated for use with the Metafix Hip Stem and the Bipolar Head is indicated with any Corin 12/14 taper hip stem.

12. Non-Clinical Testing:

A comparison of design, materials, size range, and indications for use demonstrate substantial equivalence with the predicate components. Testing was submitted in the predicate 510(k) submissions and as demonstrated in the substantial equivalence table, the Metafix Femoral Stem, when coupled with the Corin hip hemi-arthroplasty heads is substantially equivalent to the predicate devices and expected to be safe and effective for the proposed indications.

13. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Metafix Femoral Stem for total hip arthroplasty and the Metafix Femoral Stem for Hemi–arthroplasty.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Corin U.S.A.
% Ms. Lucinda Gerber
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MAY - 4 2012

Re: K120362
Trade/Device Name: Metafix Femoral Stem for Hemi-Arthroplasty
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: LZO, KWL, KWY
Dated: February 3, 2012
Received: February 6, 2012

Dear Ms. Gerber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K 120362

Device Name: Corin Metafix Femoral Stem

Indications for Use:

The indications for the Corin Metafix Hip Stem as a total hip arthroplasty and, when used in combination with Corin hemi-arthroplasty femoral heads, as a hemi-arthroplasty, include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur
- Developmental dysplasia of the hip (DDH) and congenital dysplasia of the hip (CDH)

The Corin Metafix Hip Stem is indicated for cementless use only.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120362